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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,243	08/26/2003	Jean-Christophe Leroux	017753-165	1768

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EXAMINER

TSAY, MARSHA M

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/647,243

Applicant(s)

LEROUX ET AL.

Examiner

Marsha M. Tsay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-12,14-18 and 22-28 is/are rejected.
- 7) ☒ Claim(s) 9,13 and 19-21 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/29/03</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-28 are pending and under examination.

Priority: The instant application was filed August 26, 2003. This application claims priority to provisional application 60/405,720, filed August 26, 2002, and foreign priority to PCT/FR03/00797, filed March 12, 2003. The foreign application has been submitted. The priority date is August 26, 2002.

Specification

The disclosure is objected to because of the following informalities: the priority information needs to be updated on pg. 1 of the specification to reflect the proper date. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 10, 14, 16-17, 22-23, 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 2-4, 10, 14, 16-17, 22-23, 25-26 are included in this rejection because they are dependent on claim 1.

Claim 27 is drawn to a process for preparing an organogel composition. It is unclear whether the process is "comprising the steps of" or is "consisting of" the steps as disclosed in the claim.

Claim 28 is objected to because it is unclear whether the "said substance" is referring to the organogelling substance or the bioactive substance. In addition, the term "sparingly" soluble renders the claim indefinite because there is no explicit definition of "sparingly" and it is uncertain to what extent and the difference in degree, if any, between a substance that is soluble as opposed to one that is "sparingly" soluble.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10-12, 14-18, 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Tarantino (WO 9408623). Tarantino teaches injectable compositions for the sustained release of biologically active proteins and polypeptides. The lecithin gel can be formed in vivo by the intramuscular or subcutaneous injection of a solution of lecithin in an organic solvent (p. 1, lines 30-32). Tarantino teach the lecithin gels are formed in vivo by absorption of water from the aqueous interstitial fluid at the injection site (p. 2, lines 1-3). Tarantino teach the injectable pharmaceutical composition which forms a lecithin gel in vivo for the sustained release of a biologically active compound to comprise of: 1) a pharmaceutically acceptable organic solvent which is not substantially

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soluble in water and which is capable of dispersing a lecithin and forming a lecithin gel upon the absorption of body fluids; 2) a biologically active compound; and 3) a lecithin dispersed in the organic solvent in an amount sufficient to cause gelation upon the absorption of body fluids (p. 3, lines 1-13; claims 1, 3). Tarantino teaches the term "lecithin" to encompass a complex mixture of acetone-insoluble phosphatides which consists chiefly of phosphatidyl choline, phosphatidyl ethanolamine, phosphatidyl serine, etc., combined with various substances such as triglycerides, fatty acids, and carbohydrates (p. 3, lines 25-30). Tarantino also teaches that the composition can contain additional substances that further stabilize the active ingredient (p. 5, lines 21-28) or comprise excipients which act to modify the properties of the lecithin gel (p. 6). Tarantino teaches an injectable composition (example 1a) containing 0.148 mL Interferon α -2a; 0.052 mL ammonium acetate pH 5.0; 6.0 g lecithin; and 14.8 g medium chain triglycerides (MCT) (p. 10, example 1; claims 1, 3, 6-8, 14-18). Tarantino teaches the MCT to comprise of fractionated coconut oil fatty acids C₈-C₁₀ which contains 50-65% caprylic acid and 30-45% capric acid, etc. (p. 5, lines 7-10; claims 10-12).

Tarantino teaches the subcutaneous administration of the composition from example 1a, containing IFN- α , to rats (p. 14, lines 5-7; claims 23-25). In Figure 1, Tarantino demonstrates that the sustained release composition of example 1a provided detectable serum levels for at least 96 hours (p. 14, lines 24-26), indicating the organogel is in a stable gel form (claim 22).

Tarantino teaches a process for preparing an injectable composition that can form a gel in vivo by intramuscular or subcutaneous injection into an animal body.

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Tarantino teaches that if the active ingredient is not readily dispersible in the lecithin/solvent mixture, the active ingredient may first be dissolved in a small amount of water or in a buffer solution (p. 7, lines 10-14; claim 26).

Although Tarantino does not teach the transition temperature of the organogel from the liquid state to the gel state, this property is inherent to the lecithin gels and meets the limitations of claims 4-5 because the lecithin organogel that Tarantino teaches, meets the limitations of claim 1, and changes from the liquid to the gel state upon injection into an animal body (p. 14, example 2).

Claim Objections

Claims 9, 13, 19-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

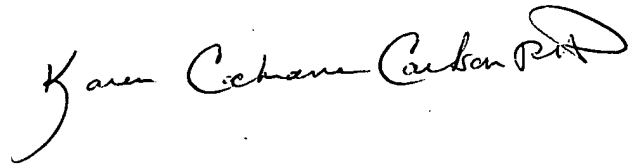
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 7, 2005

A handwritten signature in black ink, reading "Karen Cochrane Carlson". The signature is fluid and cursive, with a large, stylized initial "K".

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER